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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,970	02/14/2002	Michael Helmus	01-202	9278

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3773	
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10/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/075,970	HELMUS, MICHAEL	
	Examiner	Art Unit	
	MELANIE TYSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7,9-21 and 46-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7,9-21 and 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the applicant's amendment received 16 August 2010. The application is not in condition for allowance for the reasons set forth below. Claims 2, 4, 8, and 22-45 remain cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5-7, 9-21, and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (U.S. Patent No. 6,153,252) in view of Bolz (U.S. Patent No. 6,287,332 B1).

Hossainy discloses an implantable medical device (stent; see entire document) comprising a biodegradable inner core (for example, see column 3, lines 10-21), thus becoming decreasingly rigid upon contact with bodily fluid, a biodegradable covering material completely covering the inner core material as a coating thereon (for example,

see column 3, lines 55-58 and column 4, lines 1-14) and does not contain a therapeutic agent therein (an alternate embodiment may contain agents if desired), and one or more coating layers containing one or more therapeutic agents that may be provided on the inner core material and/or the covering material (for example, see column 7, lines 13-19), wherein the entire medical device is substantially biodegradable by the body (i.e., both the cover and inner core may be biodegradable). The covering material may be formed of a hydrophobic surface erodable polymer (for example, polyamide, polyorthoester, or polyanhydride; for example, see column see 5, lines 6-12), thus is capable of controlling the rate at which the inner core material becomes flexible upon contact with bodily fluids. Hossainy discloses the inner core may be metallic, an absorbable plastic, or any other suitable material which can provide the necessary mechanical requirements of a stent, but fails to disclose the biodegradable inner core material is specifically selected from biodegradable metallic or ceramic materials.

Bolz discloses an implantable medical device, such as a bioresorbable stent (see entire document). Bolz teaches constructing the bioresorbable stent of degradable metallic materials. Bolz further teaches that stents of degradable metallic material combine the advantageous mechanical properties of metal stents (such as elasticity, deformability, and stability by way of improving ductility, tensile strength, etc.; for example, see column 3, lines 11-35) with the bioresorbability of polymer-based stents (for example, see column 2, lines 6-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form Hossainy's inner core

from a biodegradable metallic material as taught by Bolz. Doing so would provide the mechanical advantages described above.

With further respect to claims 7, 10, and 50, such materials are well known in the art and thus it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the inner core and covering from the materials recited, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With further respect to claims 11-13, Hossainy discloses the inner core material may comprise a cylindrical stent with perforated passages, a cylindrical structure formed of helical wound or serpentine wire structures, or a rolled tubular structure that is woven, wrapped, drilled, etched, or cut to form passages. Hossainy fails to disclose whether the filaments utilized are monofilaments or multifilaments. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the inner core comprising either monofilaments or multifilaments, since such configurations are well known in the art and the applicant has failed to disclose that such configurations provide an advantage, are used for a particular purpose, or solve a stated problem. It appears the invention would perform equally well with any configuration, including configurations disclosed by Hossainy.

Claim 15 is being treated as a product by process limitation, in that “the tubular structure is micromachined or laser-cut” refers to the process of forming the tubular structure and not to the final product created. As set forth in MPEP 2113, “Even though

product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, a stent as described above wherein the tubular body is formed by micromachining or laser-cutting is directed to the method of making the stent and not to the final product made. It appears that the product disclosed by Hossainy in view of Bolz would be the same as that claimed, especially since both applicant's product and the prior art product have the same final structure of a biodegradable inner tubular structure and a biodegradable covering material.

With further respect to claims 19-21, the stent of Hossainy in view of Bolz is capable of being used as claimed if one so desires.

With further respect to claims 46 and 47, Bolz recognizes stents for some applications are only needed for a few months, thus a degradable metallic material that decomposes within a period of some months are advantageous (for example, see column 1, lines 44-47 and column 2, lines 21-23). Hossainy recognizes absorption rates of the polymeric covering materials may be adjusted as needed (for example, see column 7, lines 18-55). Therefore, would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the covering material of the

device such that the entire device has adequate rigidity from about three to about six months, or about one month to three months, and that is completely biodegradable within about six months to one year, or about three months to six months, following implantation, if the intended application required such characteristics, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 16 August 2010 have been fully considered but they are not persuasive. The applicant argues that there would be no good reason to provide the coating of Hossainy on Bolz's device, and further that doing so would add to manufacturing cost and complexity and thus would be undesirable. However, as described in the previous office action, Hossainy discloses the inner core material may be metallic, an absorbable plastic, or any other suitable material which can provide the necessary mechanical requirements of a stent. Hossainy fails to disclose the biodegradable inner core material is specifically selected from biodegradable metallic or ceramic materials. Bolz discloses an implantable medical device, such as a bioresorbable stent (see entire document). Bolz teaches constructing the bioresorbable stent of degradable metallic materials. Bolz further teaches that stents of degradable metallic material combine the advantageous mechanical properties of metal stents (such as elasticity, deformability, and stability by way of improving ductility, tensile strength, etc.; for example, see column 3, lines 11-35) with the bioresorbability of

polymer-based stents (for example, see column 2, lines 6-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form Hossainy's inner core from a biodegradable metallic material as taught by Bolz. Doing so would provide the mechanical advantages described above. The burden was placed on the applicant to provide reasons as to why the biodegradable metallic material would not be suitable for use in Hossainy's inner core. Since the applicant failed to provide arguments as to why it would not have been obvious to one having ordinary skill in the art to form Hossainy's inner core from a biodegradable metallic material, it is the examiner's position that such a modification would have been obvious to one having ordinary skill in the art given the advantages taught by Bolz, and thus the rejection stands.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062 and e-mail address is melanie.tyson@uspto.gov. The examiner can normally be reached on Monday through Thursday 8-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Examiner, Art Unit 3773
October 21, 2010